



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 9/007, A61B 17/12	A1	(11) International Publication Number: WO 99/37260 (43) International Publication Date: 29 July 1999 (29.07.99)
(21) International Application Number: PCT/NL99/00023 (22) International Filing Date: 15 January 1999 (15.01.99) (30) Priority Data: 1008090 22 January 1998 (22.01.98) NL (71)(72) Applicant and Inventor: LUBBERMAN, Bernardus, Henricus, Maria [NL/NL]; De Aa 60, NL-7642 HD Wierden (NL). (72) Inventors; and (75) Inventors/Applicants (for US only): VERVAET, Charles, Johannes, Wilhelmus, Clements [NL/NL]; Roos Vosstraat 11, NL-3123 SV Schiedam (NL). WAAYMAN, Gerrit, Jan [NL/NL]; Van Royensweg 21B, NL-7691 BP Bergentheim (NL). (74) Agent: SEERDEN, Adrianus, Maria; Octrooibureau Vriesendorp & Gaade, Dr. Kuyperstraat 6, NL-2514 BB Den Haag (NL).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>In English translation (filed in Dutch).</i>
(54) Title: PLUG FOR CLOSING OFF A TEAR-DUCT <div style="text-align: center;"> </div> (57) Abstract <p>Plug (1) for closing off a tear-duct (12) which plug (1) is provided with two extremities. The plug (1) has a shaft (2) which at one of the two extremities is provided with a broadened head (3) with a lower surface and an edge. The lower surface has an at least partially bent shape. The shaft (2) comprises a broadened part (4) which slopes in the direction of both extremities. The broadened head (3) has a hollow curvature (7) and the edge of the broadened head (3) is bent back in the direction of the broadened part. The plug (1) is made of a moist absorbing material which is not soluble in water, for instance a modified HEMA, to which substances have been added for increasing the moist absorption and an inflammation inhibitor, for instance heparin.</p>		

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Plug for closing off a tear-duct

The invention relates to a plug for closing off a tear-duct, which plug is provided with two extremities, with a shaft which at one of the two extremities is provided with a broadened head with a lower surface and an edge, the lower surface having at least a partially bent shape, the shaft having a broadened part which
5 slopes in the direction of both extremities.

Such a plug is known from the US patent specification 5.334.137.

10 Tear-ducts serve to discharge tear-water from an eye to the nasal cavity. Two tear-ducts end near each eye which ducts usually have a diameter of about 0.3 mm and are surrounded by a ring of connective tissue. Via the tear-duct opening or punctum and the tear-ducts or canaliculi tear-water is discharged to the tear-bag and from there to the nasal cavity.

15 Tear-water among others serves to discharge dust and dirt and to keep the eye clean and moist. Tear-water also contains among other the enzyme lysozyme which acts as a kind of antibiotic and which protects the eye from infections. Per day a normal eye produces about 400 drops of tear water. During sleeping the tear-water production is lower.

20 A shortage of tear-water may for instance occur as a result of excessive discharge via the tear-ducts. An unfavourable composition of the tear-water may also cause these problems, for instance when too little sebaceous matter is produced and the tear-water is too watery as a result of which it evaporates more quickly. Circumstances which may aggravate the symptoms of dry eyes are for instance
25 working in dry environments with a low air humidity, such as air-conditioned environments or air-planes, or working with computers.

Moistening the eye is promoted by fully fluttering the eyelids. However, this

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flutter reflex is reduced with some people, for instance contact lens wearers, as a result of which the symptoms of dry eyes occur earlier with these people. The symptoms of dry eyes may also occur when too little tear-water is produced. The production of tear-water decreases when getting older. Thus the tear-water
5 production at the age of 65 is on an average 60% lower than at the age of 18.

By wearing contact lenses the evaporation of tear-water is accelerated. This may cause irritation or give reason for the deposit of protein or infections. Because in many quarters, for instance offices, the air humidity is kept low by means of
10 climate control systems, more and more people, particularly wearers of contact lenses, suffer from these symptoms.

Dry eyes can be prevented or at least partially be remedied by reducing the discharge of tear water via the tear-ducts by arranging a little plug in one of the
15 tear-ducts, or in serious cases in both tear-ducts, as a result of which the discharge of tear-water is blocked. Disadvantages of the known tear-duct plugs however are that they are difficult to arrange and have to be arranged by an ophthalmologist or ophthalmic educated personnel.

20 The tear-duct plug known from the US patent 5.334.137 may in some cases move during use, and appeared not always to sufficiently close off the tear-duct.

The object of the invention is to provide a plug for a tear-duct, which during use remains on the same location and which sufficiently closes off the tear-duct.
25

The object of the invention is achieved with a plug of the kind mentioned in the preamble, which has said broadened head and hollow curvature, and that the edge of the broadened head is bent back in the direction of the broadened part. With this measure it is achieved that the broadened head attaches itself firmly like
30 a suction cup to the moist mucous membrane tissue surrounding the opening of the tear-duct. In this way the plug is durably and firmly kept in its place after insertion in the tear-duct. The head of the plug known from the US patent specification does not have a bent back edge, so that no sucking effect is obtained.

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In a preferred embodiment the plug is made of a moist absorbing material which is not soluble in water, such as for instance HEMA, of which also contact lenses are made. HEMA is a moist absorbing synthetic which does not irritate the eyes and mucous membranes. Moreover HEMA is radio opaque so that it can be perceived with the help of for instance X-ray equipment, whereas the little plug is virtually invisible with the naked eye. Preferably the HEMA is modified and substances are added for increasing the moist absorption. A modified HEMA may swell with a factor 1.4 as a result of moist absorption. In a preferred embodiment an inflammation inhibitor, for instance heparin, may also be added to the material from which the plug is made.

The plug is easier to remove if at the side facing the head, the broadened part of the shaft changes with a gradual running bend into a substantially cylindrical part of the shaft.

Preferably the tear-duct plug is provided with a cavity which from the broadened head tapers off in the longitudinal direction of the plug. In this way it is achieved that the plug can be arranged or removed in a simple manner with the help of a pair of tweezers or such like tools. If, as in most cases, the tear-duct has to be completely closed off, this cavity has to be a blind cavity. If the discharge via the tear-duct has to be reduced but not entirely closed off, then a passage can be arranged contiguous to this cavity which passage continues to the extremity opposite the broadened head.

The invention will be elucidated on the basis of the drawing, in which:

Figure 1 shows a plug according to the invention in perspective;

Figure 2 shows a human eye provided with a plug in accordance with figure 1;

Figure 3 shows a cross-section of a plug along the line III-III from figure 1; and

Figure 4 shows a cross-section of another embodiment of a plug according to the invention.

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Figure 1 shows a tear-duct plug 1 according to the invention, consisting of a shaft 2 with a broadened head 3 which serves to abut the tissue surrounding the tear-duct opening after placing the plug 1 in a tear-duct. The broadened head 3 has an edge. The other extremity is formed by a broadened part 4 which on the one hand shows a conical course and ends in a pointed extremity 5. On the other hand the broadened part 4 preferably merges with a gradual bend into a substantially cylindrical part 6 of the shaft 2. The broadened head 3 is substantially dish-shaped, shows a hollow curvature 7, and the edge of the broadened head 3 is bent back in the direction of the broadened part 4, as can clearly be seen in figure 3 in which the plug 1 is shown in cross-section. As a result of this hollow curvature and bending back the broadened head attaches itself firmly like a suction cup to the tissue surrounding the opening or punctum 9 of the a tear-duct or canaliculus 10 to be closed off.

In figure 2 a part of an eye 11 is shown, in which the tear-duct 10, namely a lower tear-duct 12 and an upper tear-duct 13, are shown in dotted lines. The tear-ducts 12, 13 consist of a substantially vertical part 14 of about 2 mm long and contiguous to it a substantially horizontal part 15 of about 8 mm long, which connects to the tear-bag 16. To dam the discharge of tear-water via the tear-ducts 12, 13 in figure 2 a plug 1 is arranged in the lower tear-duct. The broadened head 3 protrudes from the tear-duct 12 and abuts the tissue surrounding the tear-duct opening 9. The broadened part 4 is in the tear-duct 12. The tissue of the inner wall of the tear-duct clamps around the broadened part 4, as a result of which because of the sucking effect of the broadened head 3 the plug can less easily slide of its own accord. Because the broadened part 4 is gradually bevelled towards both extremities the plug can both be placed and removed easily.

Because the tear-duct plug 1 is made of a moist absorbing material, for instance a modified HEMA, the plug 1 swells after insertion in the tear-duct. By means of additives the factor with which the modified HEMA swells, can be increased to a swell factor of about 1.4. In figure 3 the plug 1 in the unswollen situation immediately after insertion in the tear-duct is shown in dotted lines. In full line the same plug 1 is shown after it has swollen to its maximum size. As a result of the

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swollen size of the plug, the plug 1 remains much more firmly in its place in the tear-duct 10.

5 The plug 1 further comprises a blind cylindrical cavity 17 which from the broadened head 3 extends in longitudinal direction of the plug 1. By means of said cavity 17 the plug can be placed or removed with the help of a suitable tool.

10 In figure 4 another possible embodiment of a tear-duct plug according to the invention is shown in which contiguous to the cavity 17 a passage 18 is arranged which ends at the pointed extremity 5 of the plug 1. Such a plug can be used if the discharge of tear-water via the tear-duct should not be entirely impeded, but only partially.

Claims

1. Plug (1) for closing off a tear-duct (12), which plug (1) is provided with two extremities, with a shaft (2) which at one of the two extremities is provided with a broadened head (3) with a lower surface and an edge, the lower surface having at least a partially bent shape, the shaft (2) having a broadened part (4) which slopes in the direction of both extremities, **characterized in that** the broadened head has a hollow curvature (7), and that the edge of the broadened head (3) is bent back in the direction of the broadened part.
2. Plug (1) according to claim 1, **characterized in that** the plug (1) is made of a moist absorbing material which is not soluble in water.
3. Plug (1) according to claim 2, **characterized in that** the plug (1) is made of HEMA.
4. Plug (1) according to claim 2, **characterized in that** the plug (1) is made of a modified HEMA, to which substances have been added for increasing the moist absorption.
5. Plug (1) according to any one of the preceding claims, **characterized in that** the plug (1) is made of a material to which an inflammation inhibitor, for instance heparin, is added.
6. Plug (1) according to any one of the preceding claims, **characterized in that** at the side facing the head (3) the broadened part (4) of the shaft (2) changes with a gradual running bend into a substantially cylindrical part of the shaft (2).
7. Plug (1) according to any one of the preceding claims, **characterized in that** the plug (1) is provided with a cavity (17) which from the broadened head tapers off in the longitudinal direction of the plug (1).

8. Plug according to claim 7, **characterized in that** contiguous to the cavity (17) a passage (18) is arranged which runs through to the extremity across the broadened head.

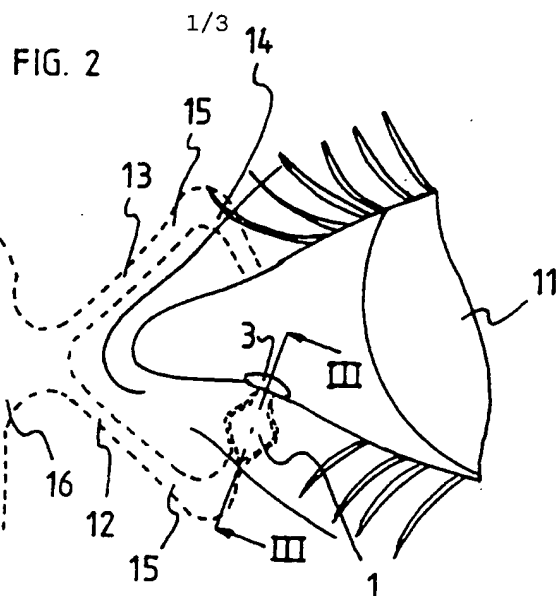


FIG. 1

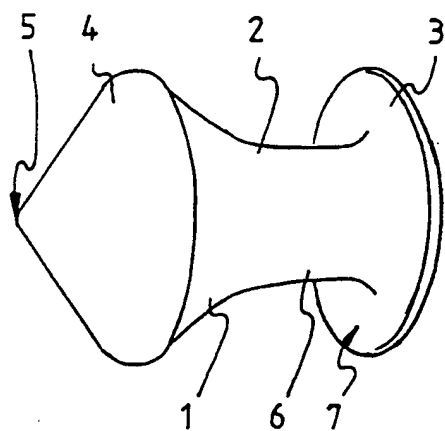
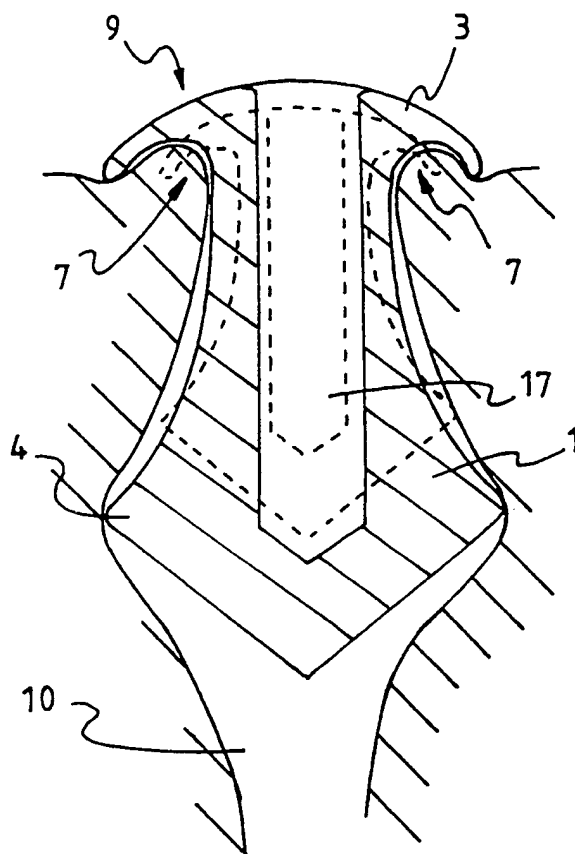
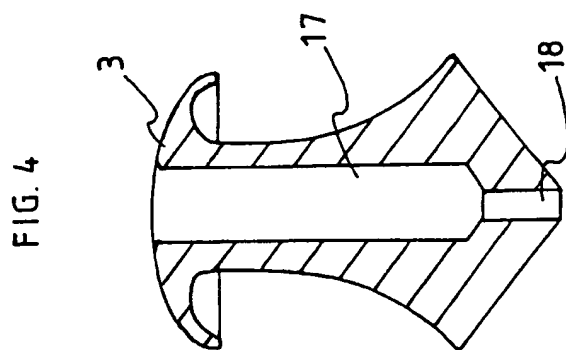


FIG. 3





INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 99/00023

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F9/007 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B F16L F16B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 334 137 A (FREEMAN JERRE M) 2 August 1994 see column 8, line 10 - line 32; figure 9 ---	1,6,7
A	US 5 283 063 A (FREEMAN JERRE M) 1 February 1994 see column 12, line 27 - line 60; figures see column 15, line 40 - column 16, line 19 ---	1-3,6,7
A	US 2 737 953 A (WILTEIN) 13 March 1956 see figures ---	1,6,7
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Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 91 14406 A (HERRICK ROBERT S) 3 October 1991 see page 12, line 25 - page 13, line 7; figures</p> <p>-----</p>	1

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Information on patent family members

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